DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 9, 15, 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893).

Considering Claims 7, 9, and 18: Langer et al. teaches a method of making a semi-interpenetrating network (3:5-21) comprising a blend of ionically and covalently crosslinkable polymers where the covalently crosslinkable polymer is crosslinked (10:8-20). Langer et al. teaches the ionically crosslinkable polymer as optionally being hyaluronic acid (4:50-5:2) and the covalently crosslinkable as optionally being a water soluble chitosan (6:46-50). Since Langer et al. teaches the ionic compound as not being crosslinked, the reaction conditions would inherently be such that the amine groups would not be protonated, and the hydroxyl groups are not reacted, as these would result in the crosslinking of the hyaluronic acid.

Langer et al. does not teach the combination of chitosan and an anionic polysaccharide with sufficient specificity. However, Langer et al. does teach each of the components as being one of a finite number of possible alternatives. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the combination of chitosan and an anionic polysaccharide, and the motivation to do so would have been that it is obvious to choose from a finite list of predictable, known options with a reasonable expectation of success. See MPEP § 2143.

Langer et al. does not teach the claimed pH. However, Langer et al. does teach that the pH affects the degree of crosslinking of ionically crosslinkable polymers (1:27-29). Generally, differences in reaction conditions are not sufficient to support patentablility. See MPEP § 2144.05. It would have been obvious to a person having ordinary skill in the art at the time of invention to have optimized the pH through routine optimization, and the motivation to do so would have been, as Langer et al. suggests, to reduce the crosslinking of the ionic component (1:27-29), thus providing a semi-interpenetrating network which has advantageous degradation properties and enhance mechanical properties (10:8-20).

Considering claims 15 and 16: Langer et al. teaches using chitosan (6:46-50). Chitosan is by definition deacetylated chitin. As deacetylated chitin is listed as a derivative of chitosan in claim 16, chitosan would then fall under the scope of derivative of chitosan as presented in the claims.

Considering Claim 19: Langer et al. teaches the network as additionally comprising other components of the extra cellular matrix in a blend with hyaluronic acid (4:1-8).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893) as applied to claim 7 above, and further in view of the evidence of Hudson et al. (Chitin and Chitosan).

Considering Claim 17: Langer et al. teaches the method of claim 7 as shown above. Langer et al. also teaches the chitosan as being soluble in water (6:46-50).

Langer et al. is silent towards the acetylation content of the chitosan. However, "[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05. As Hudson et al. shows that the acetylation degree of the chitosan is directly related to the solubility of the chitosan in water (Section 4.1), a person having ordinary skill in the art at the time of invention would consider the acetylation degree to be a result effective variable. As such, it would have been obvious to a person having ordinary skill in the art at the time of invention to have optimized the acetylation content of the chitosan of Langer et al. through routine optimization, and the motivation to do so would have been to obtain a water soluble chitosan for the crosslinking reaction.

Response to Arguments

Applicant's arguments filed October 16, 2009 have been fully considered but they are not persuasive, because:

A) The applicant's argument that Langer et al. does not teach a semi-interpenetrating network wherein hyaluronic acid is not crosslinked is not persuasive. Langer et al. teaches forming a semi-interpenetrating network between an ionically crosslinkable polymer and a covalently crosslinkable polymer (10:8-20). This section further describes one of the components as the "non-crosslinked" polymer. The use of the word "crosslinkable" is not identical to the term "crosslinked", as the applicant contends. Langer et al. explicitly defines a semi-interpenetrating network as "solutions that include two independent components, where one component is a crosslinked polymer and the other component is a non-crosslinked polymer".

As such, a person having ordinary skill in the art at the time of invention would understand that in a semi-interpenetrating network between an ionically crosslinkable polymer and a covalently crosslinkable polymer one of the components would be crosslinked and one component would be non-crosslinked. As there are only two options, a person having ordinary skill in the art at the time of invention would immediately envision and embodiment where the ionically crosslinkable polymer is not crosslinked. Although Langer et al. admittedly does not explicitly teach using hyaluronic acid as the non-crosslinked component of a semi-interpenetrating network, Langer et al.

suggests using hyaluronic acid as the ionically crosslinkable component of a semi-interpenetrating network, and suggests using the ionically crosslinkable component as the non-crosslinked component of the semi-interpenetrating network. "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01.

B) The applicants argument that the teaching of Langer et al. does not suggest the pH range of 7 to 8 is not persuasive. Langer et al. teaches pH as being a result effective variable to control the amount of crosslinking of an ionically crosslinkable polysaccharides. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05. As such, it would have been obvious to a person having ordinary skill in the art at the time of invention to have optimized the pH through routine optimization, and the motivation to do so would have been, as Langer et al. suggests, to reduce the crosslinking of the ionic component (1:27-29).

C) The applicants argument that chitosan is not soluble at a pH of 7 to 8 is not persuasive. Hudson et al. teaches that chitosans having a degree of acetylation of around 50% are soluble at a pH of 7 (Section 4.1). As Langer et al. requires a water soluble chitosan (6:46-50), a person having ordinary skill in the art at the time of invention would be motivated to choose a chitosan soluble at a pH of 7, as described by Hudson et al. .

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796

LJH
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